International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

August 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Docket No. 02N-0277 - Section 306: Bioterrorism Preparedness; Establishment & Maintenance of Records

To the Dockets Management Branch:

The International Dairy Foods Association (IDFA) is submitting these comments on implementation of Section 306 of Public Health Security and Bioterrorism Preparedness and Response Act of 2002. IDFA's comments on the administrative detention provisions are submitted on its own behalf, and on behalf of its constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute which represent approximately 850 members who operate more than 1550 processing facilities and produce eighty-five percent of all dairy products consumed in the United States.

In general, IDFA strongly supports the provisions of the Act and FDA's critical role of ensuring the safety and wholesomeness of the American food supply and consumer confidence in the food safety system. In addition to support for the Act's mission, dairy processors offer the following comments and suggestions on Section 306 – Establishment & Maintenance of Records. To assist FDA in the promulgation process, IDFA raises the following issues and provide our perspective:

1. What constitutes reasonable belief?
2. Will FDA share the basis or underlying facts of its reasonable belief?
3. How does FDA expect to records handle commingled ingredients and packaging?
4. What is the appropriate retention time for records?
5. Will FDA have access to consumer complaints and other records?

1250 H Street, N.W., Suite 900, Washington, DC 20005
telephone: 202-737-4332 fax: 202-331-7820

Issue #1 -- What constitutes a reasonable belief?

The Act calls for facilities to provide access to and allow copying of records when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. IDFA and facilities that will be subject to the new regulation seek clarification of what constitutes a reasonable belief. IDFA and dairy processors realize that a precise definition is difficult to establish and needs to be flexible, but, IDFA and dairy processors would appreciate some indication as to the level of information that would be required to trigger an investigation into records by the FDA.

IDFA's belief is that "reasonable information" is a lower level of information than "a preponderance of information" which is usually characterized as "more than 50% likelihood of a predictive outcome" or otherwise interpreted as "more likely than not, that the event will occur." By contrast, beyond a reasonable doubt is usually characterized as approximately a 90 to 95% certainty that an event has or will take place. IDFA and dairy processors would appreciate it if FDA would address this issue and to the degree possible put the concept of reasonable in its appropriate context.

Issue #2 – Will FDA share the basis or underlying facts of its reasonable belief?

IDFA would like to take this opportunity to encourage FDA to be as open as possible with the disclosure of any and all information to a facility or facilities where FDA has a reasonable belief that food from the facility or facilities presents a threat of serious adverse health consequences or death to humans or animals. IDFA asserts that the more forthright FDA is in disclosing the basis of its belief, the more helpful a facility can be in either verifying or dispelling that belief. This is particularly true when a situation is presented to FDA that is vague enough so that copious quantities of records would need to be accessed and where undoubtedly a short timeframe exists in which critical decisions must be made.

In an analogous and related situation, the Federal Bureau of Investigation (FBI), the Central Intelligence Agency (CIA) and other federal agencies arrived at that precise conclusion prior to the creation of the Food Industry Information Sharing and Analysis Center (Food ISAC) which is housed within the National Infrastructure Protection Center (NIPC). The Food ISAC, one of eight ISAC's, exists as a two-way conduit for the flow of sensitive information regarding potential terrorist attacks on the food supply and allows for the flow of sanitized intelligence information to the affected trade associations, companies and facilities. Those associations, companies and facilities then provide perspective and additional information so that an informed assessment of a threat can be properly made. IDFA believes FDA has the authority to proceed in a similar manner.

Issue #3 -- How does FDA expect to records handle commingled ingredients and packaging?

IDFA is concerned with how FDA interprets the need for records that will permit FDA to identify the immediate previous sources and recipients of food and its packaging,

particularly since many foods, ingredients, and packaging materials are commingled at some point, which diminishes the ability to trace the source or recipient on a molecular basis. Consider for example, liquid sugar that is used by dairy processors and numerous other food processors. It is delivered to processing operations by truck and by rail and is frequently pumped into a storage tank where it is held and used on an ongoing basis. The tank is rarely ever empty and shipments are sourced from more than one supplier. As such, they become commingled and it is impossible to distinguish the particular source of any particular gallon, cup, or molecule of that liquid sugar as it is used as an ingredient in a particular food. Liquid sugar is by no means the exception, rather it is a typical example of a situation that occurs repeatedly on a day-to-day basis. Packaging materials are no exception.

IDFA asserts that facilities should maintain records that show the sources from which the food and its packaging components are derived. The language of the statute specifically states "sources" which is the plural form of source. IDFA asserts that allowing a facility to identify one or several sources of a food's or packaging's components meets the Act's requirements and is in fact the only reasonable and pragmatic manner in which to construct the requirement. For clarity, FDA should acknowledge in its regulation that the requirements of the regulation are satisfied by providing to FDA the name or names of the sources of the components (food and its packaging) and that there is no need to attempt to identify items down to the molecular level. Specifically, by example, if FDA asked a facility to identify the source of the sweetener in a half-gallon of its cherry vanilla ice cream, a facility's response that it purchased its liquid sugar from both the ABC Company and the XYZ Company, should be acceptable.

IDFA anticipates that FDA will receive substantial comments on this particular issue and has given it the utmost consideration. Thus far, IDFA's proposed response here is the only logical and viable option we have been able to formulate. To require more specificity would require costly and burdensome changes in the way most food processors operate. If FDA desires to mandate such requirements, this is not the regulation with which to act upon those desires. Similarly, if FDA is interested in linking foods flowing out of a facility with specific sources ingredients flowing into a facility, that is an issue that is also difficult or impossible to do in most food processing operations. Again, rather than to attempt to resolve the issue in the forthcoming proposed rule, FDA should raise its concern and address it in a separate rulemaking where there will be a full and fair opportunity to explore the issue properly.

Issue #4 -- What is the appropriate retention time for records?

The statutory maximum for record retention under the Act is two years. IDFA would assert that Congress's intention was for FDA determine a lesser period which would meet the requirements of its objective. IDFA would further assert that the relevant timeframe for record retention varies depending on the record in question and the food product that is being scrutinized. In particular, IDFA and dairy processors do not believe that record retention for a period of two years makes sense for many products that have a useful or shelf life of a considerably shorter duration. The sell by date for fluid milk is frequently as short as 14 days. IDFA does not believe that it would be logical to retain records for a

period of two years for a product that will undoubtedly be consumed or disposed of within a matter of weeks. This is especially true where the sole purpose of the record retention is to assist in determining whether or not the food presents a threat of serious adverse health consequences or death to humans or animals. With all respect, after the product is consumed or disposed of, a threat no longer exists and records being keep for the sole purpose of threat analysis are not longer meaningful.

Therefore, IDFA suggests that FDA adopt a timeframe for record retention that links the timeframe of record retention to the timeframe for a meaningful threat analysis. In particular, IDFA suggests that for all foods that bear a *sell by* or *use by* date, the period of record retention is 90 days beyond the sell by or use by date. IDFA believes the majority of food products already have that type of information stamped on the product's packaging, leaving FDA only to determine a timeframe for products whose shelf is arguably considerably longer.

Issue #5 – Will FDA have access to consumer complaints and other records?

IDFA and dairy processors are somewhat concerned that government officials may view the Act as authority to inspect anything and everything that is not specifically excluded by statute. The statute specifically states all records relating to the manufacture, processing, packing, distribution, receipt, holding or importation of the article in question. The statute also specifically exempts information that Congress deemed as not being relevant for the purposes of the Act, including recipes for food, financial data, personnel data, research data, or sales data, other than shipment data regarding sales.

IDFA asserts that a number of records exist which have not been designated as being accessible or not accessible. IDFA suggests that FDA consider what additional records exist and make a determination during the promulgation of the regulation as to whether or not they will be accessible. IDFA further suggests that FDA specifically exclude consumer complaints from the universe of accessible documents.

IDFA would also like to point out that while it initially appears that the records Congress labeled, as being accessible, is broad, it is in fact qualified. In particular, Congress qualified accessibility to those records that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. IDFA urges FDA to make it clear in its regulation that in those instances where FDA has a reasonable belief that an article of food is adulterated and presents a threat, that a review of records will in fact be limited to those records that are relevant and germane and that FDA personnel shall not have carte blanche to review everything unless excluded by statute.

IDFA would encourage FDA to make these clarifications now, so that in the event of a need, FDA and facility personnel can focus on cooperating to resolve the situation rather than spending needless time ascertaining what is or is not accessible, nor requiring FDA personnel to peruse copious quantities of unnecessary documents.

IDFA and dairy processors envision that many of the issues raised in these comments may, to a degree, be academic, because we fully anticipate that in the event of a perceived threat, industry and FDA will in all likelihood exhibit a high degree of cooperation for the benefit of all. Still, we feel it is necessary to raise the issues so that appropriate considerations can be made.

IDFA appreciates the opportunity to comment on the regulatory process involving Section 306 of the Act and stands ready to answer any questions to help achieve these important objectives of this section.

Sincerely,

Clay Detlefsen
Vice President, Regulatory Affairs & Counsel
International Dairy Foods Association